

2962 No. 15032

United States
Court of Appeals
for the Ninth Circuit

UNITED STATES OF AMERICA,

Appellant,

vs.

WAYNE A. PARKINSON, an Individual Trading
and Doing Business as Glandular Products
Company and Dybutol Company, and ALLEN
H. PARKINSON, an Individual Trading and
Doing Business as Tide Mailing Service, and
MARGARET M. WILLIS,

Appellees.

Transcript of Record

Appeal from the United States District Court for the
Southern District of California,
Central Division.

FILED

MAY 7 1956

No. 15032

**United States
Court of Appeals**
for the Ninth Circuit

UNITED STATES OF AMERICA,

Appellant,

vs.

WAYNE A. PARKINSON, an Individual Trading
and Doing Business as Glandular Products
Company and Dybutol Company, and ALLEN
H. PARKINSON, an Individual Trading and
Doing Business as Tide Mailing Service, and
MARGARET M. WILLIS,

Appellees.

Transcript of Record

**Appeal from the United States District Court for the
Southern District of California,
Central Division.**

INDEX

[Clerk's Note: When deemed likely to be of an important nature, errors or doubtful matters appearing in the original certified record are printed literally in *italic*; and, likewise, cancelled matter appearing in the original certified record is printed and cancelled herein accordingly. When possible, an omission from the text is indicated by printing in *italic* the two words between which the omission seems to occur.]

PAGE

Affidavits in Support of Prayer for Temporary Restraining Order:

Ebert, Dr. Carl E.	24
Lawson, Dr. Homer C.	20
McGinnis, Dr. James Edward	26
Westrem, Winifred	33
Whittington, Dick	30
Wood, Gordon R.	18

Affidavit in Support of Preliminary Injunction:

Hirsch, Dr. Edwin W.	37
Attorneys, Names and Addresses of	1
Certificate by Clerk	87
Complaint	3
Final Consent Judgment as to Permanent In- junction Only	62
Final Judgment Denying Plaintiff's Prayer for Restitution	85
Minute Order Dated July 25, 1955	73
Notice of Appeal From Final Judgment	87

INDEX	PAGE
Notice of Appeal From Order Granting and Decree of Preliminary Injunction	60
Opinion	74
Order Extending Temporary Restraining Order	43
Order Granting and Decree of Preliminary Injunction	57
Order to Show Cause	36
Preliminary Findings of Fact and Conclusions of Law	44
Statement of Points on Which Appellant Intends to Rely on Appeal	90
Stipulation for Dismissal of Appeal	61
Stipulation and Order Re Issue of Restitution	71
Stipulation and Order for the Use of Original Exhibits in Lieu of Printing	91
Temporary Restraining Order	34

NAMES AND ADDRESSES OF ATTORNEYS

Attorney for Appellant:

LAUGHLIN E. WATERS,
U. S. Attorney;

MAX F. DEUTZ,
Assistant U. S. Attorney,
Chief Civil Division,
600 Federal Building,
Los Angeles 12, California.

Attorney for Appellee:

DANIELS, ELSON & MATHEWS,
Suite 711,
541 South Spring Street,
Los Angeles 13, California.

In the United States District Court for the
Southern District of California, Central Division
Civil Action No. 16415-C

UNITED STATES OF AMERICA,

Plaintiff,

vs.

WAYNE A. PARKINSON, an Individual Trading
and Doing Business as GLANDULAR PROD-
UCTS COMPANY and DYBUTOL COM-
PANY, and ALLEN H. PARKINSON, an In-
dividual Trading and Doing Business as TIDE
MAILING SERVICE, and MARGARET M.
WILLIS,

Defendants.

COMPLAINT FOR INJUNCTION

The United States of America, plaintiff herein, by
and through Laughlin E. Waters, United States At-
torney for the Southern District of California, Cen-
tral Division, files this Complaint for Injunction
and respectfully represents unto this Honorable
Court as follows:

(1) This proceeding is brought under Section
302(a) of the Federal Food, Drug, and Cosmetic
Act [21 U.S.C. 332(a)], hereinafter referred to as
“the Act,” specifically investing the several United
States District Courts with jurisdiction to enjoin
and restrain violations of Section 301 of said Act
[21 U.S.C. 331] as hereinafter more fully appears.

(2) The defendants, Wayne A. Parkinson, an individual trading and doing business as Glandular Products Company and Dybutol Company at 1065 and 1067 East Anaheim Street, Long Beach 13, California, and Allen H. Parkinson, [2*] an individual trading and doing business as Tide Mailing Service at 1065 and 1067 East Anaheim Street, Long Beach 13, California, and Margaret M. Willis, operating manager of Tide Mailing Service at the aforesaid addresses, are the interstate promoters and distributors of articles designated by name as:

- (a) Adler's Compound Standard Strength,
- (b) Adler's Compound Super Strength,
- (c) Vita-Glan Male Formula, Regular Strength,
- (d) Vita-Glan Male Formula, Double Strength,
- (e) Bio-Glan Male Formula, Regular Strength, together with Bio-Glan Fortified Wheat Germ Oil, and
- (f) Bio-Glan Male Formula, Double Strength, together with Bio-Glan Fortified Wheat Germ Oil.

Each of said articles is a drug within the meaning of Section 201(g) of the Act [21 U.S.C. 321(g)].

(3) Defendants Wayne A. Parkinson and Allen H. Parkinson are brothers. The promotion and distribution of the aforesaid drugs are carried out as

*Page numbering appearing at foot of page of original Certified Transcript of Record.

a mail-order business conducted in the name of Glandular Products Company and Dybutol Company, both of which are owned by Wayne A. Parkinson. These two companies have no employees.

(4) Substantially all of the normal business functions of said companies—including the printing, addressing, and mailing of labeling of the aforesaid drugs; the maintenance of extensive mailing lists which defendants have compiled or purchased over a period of years and which include the names and addresses of individuals who have responded in the past to magazine and newspaper advertisements promoting drugs and devices for sexual rejuvenation; the receipt and processing of mail orders for said drugs; the bottling, packaging, and labeling of said drugs; the addressing and shipping of said drugs in response to said mail orders; the maintenance of business records—are performed or arranged for by the Tide Mailing Service.

(5) Said Tide Mailing Service is the fictitious name of an unregistered and unincorporated business operated by Allen H. Parkinson and managed by Margaret M. Willis. The premises occupied by Glandular Products Company and [3] Dybutol Company, at 1065 and 1067 East Anaheim Street, Long Beach, California, are utilized by said Tide Mailing Service in transacting the business operations for said companies as described in paragraph (4) above.

(6) On July 13, 1949, said Allen H. Parkinson, an individual then trading as Hudson Products

Company, was convicted in this Court on four Counts for the distribution of misbranded male and female sex hormones in violation of the Act. [Cause No. 20642-Criminal]. The hormones there involved included methyl testosterone tablets and alpha-estradiol tablets. Said hormones had been offered by said Allen H. Parkinson in a widespread mail-order promotion in which he claimed that said hormones had remarkable powers of sexual rejuvenation. In announcing judgment of conviction, this Court stated it was convinced beyond a reasonable doubt that these hormone preparations constituted not merely a potential danger but also an actual danger to health when used indiscriminately by the lay person. This Court also stated that the therapeutic claims which said Allen H. Parkinson had made for these products far exceeded the benefits that could be derived from them.

(7) In less than a month after the aforesaid conviction, said Allen H. Parkinson, then doing business through the Hudson Products Company, a corporation, and its wholly owned subsidiary, Maywood Pharmacal Company, a fictitious name, again embarked upon a widespread mail-order promotion of drugs containing methyl testosterone. While the composition of said drugs was altered by the addition of Vitamin B1 and the labeling of said drugs was modified, said Allen H. Parkinson continued to make substantially the same sexual rejuvenation claims as were the basis for the criminal action.

(8) On September 29, 1949, the United States filed a Complaint for Injunction in this Court [Civil Action No. 10391-HW] alleging that the aforesaid activities described in Paragraph (7) above were in violation of the Act. Upon appellate review of that case which had been consolidated with another, *United States v. El-O-Pathic Pharmacy, et al.*, 192 F.(2d) 62 (C.A. 9, 1951), said Allen H. Parkinson was permanently restrained by this Court from continuing the aforesaid mail-order sex-hormone business which was based upon sexual rejuvenation claims. [4]

(9) On September 25, 1952, Wayne A. Parkinson registered with the Los Angeles County Clerk the fictitious business name of Dybutol Company. On November 14, 1952, said Wayne A. Parkinson registered with the Los Angeles County Clerk the fictitious business name of Glandular Products Company.

(10) Said Dybutol Company and Glandular Products Company then embarked upon a mail-order promotion of a drug designated both as Vita-Glan Male Formula, Regular Strength, and as Vita-Glan Male Formula, Double Strength, said drug being offered primarily for sexual rejuvenation. Vita-Glan Male Formula, Regular Strength, and Vita-Glan Male Formula, Double Strength, are identical drugs except that the Double Strength product is recommended in twice the daily dosage of the Regular Strength. Said drug consists of vitamins in an inert glandular base. There is now pending in

this Court a 6-Count Criminal Information against Wayne A. Parkinson [Cause No. 23165-Criminal] based upon the interstate shipment of said drugs during the period of November 28, 1952, and January 22, 1953.

(11) In the latter part of 1953, defendants herein commenced a nationwide mail-order promotion of a drug designated both as Bio-Glan Male Formula, Regular Strength, and as Bio-Glan Male Formula, Double Strength, alleging their efficacy in sexual rejuvenation. Bio-Glan Male Formula, Regular Strength, and Bio-Glan Male Formula, Double Strength, are identical drugs except that the Double Strength product is recommended in twice the daily dosage of the Regular Strength. The composition of said drug is essentially the same as the aforesaid Vita-Glan Male Formula, except that capsules of wheat germ oil are included in the package.

(12) In the latter part of January, 1954, defendants initiated yet another nationwide mail-order promotion of a drug designated both as Adler's Compound Standard Strength, and as Adler's Compound Super Strength. Adler's Compound Standard Strength and Adler's Compound Super Strength are identical drugs except that the Super Strength product is recommended in twice the daily dosage of the Standard Strength. Said drug, which is also offered for sexual rejuvenation, consists of vitamins, minerals, and wheat germ oil in an inert glandular base. In this current promotion, the tens of thousands of persons who [5] are on defendants' mail-

ing list receive letters whose envelopes are postmarked London, England, and give the return address of Konrad Adler & Company, Frankfurt am Main, Germany. Such letters offer the recipient "a new and amazing medical miracle for males," Adler's Compound, which, despite subtle qualification, is represented as a new and secret German formula effective for sexual rejuvenation. European Sales Offices are declared to be located at Paris, Rome, and London. Glandular Products Company of Long Beach, California, is stated to be the sole United States distributor of said drug. Enclosed with the letter is a 4-page descriptive folder, an order form, and an air-mail business reply envelope on which is imprinted the address of Glandular Products Company. The price range per order is from \$10 to \$35.

(13) All of the drugs distributed by the defendants, including Adler's Compound, are manufactured in the United States.

(14) When the defendants cause the drug, Adler's Compound, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to this Complaint and incorporated herein:

(a) Exhibit 1—mailing envelope with return address given as "Konrad Adler & Company, Frankfurt am Main, Germany;"

(b) Exhibit 2—undated letter bearing letterhead "Konrad Adler & Company" and purported facsimile signature of Konrad Adler;

(c) Exhibit 3—4-page descriptive folder regarding the drug, Adler's Compound;

(d) Exhibit 4—order form;

(e) Exhibit 5—air mail business reply envelope addressed to Glandular Products Company;

(f) Exhibit 6a—bottle label stating in part "Adler's Compound Standard Strength;"

Exhibit 6b—bottle label stating in part "Adler's Compound Super Strength."

(15) Defendants violate Section 301(a) of the Act [21 U.S.C. 331(a)] [6] by causing the introduction and delivery for introduction into interstate commerce of the drug, Adler's Compound, with labeling as described in paragraph (14) above, which is misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading since it represents, suggests, and creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence whereas it is not efficacious for such purposes;

(b) that said drug, which is distributed in the United States by Glandular Products Company, is manufactured in Germany and is available in the United States in limited supply only, whereas said drug is manufactured in Los Angeles, California, on

order of the defendants and is available here in unlimited supply;

(c) that said drug is a new and amazing medical miracle developed by outstanding German pharmaceutical knowledge and ingenuity, whereas said drug is composed of commonly known ingredients and is not a new and amazing medical miracle;

(d) that the tablets comprising Adler's Compound, Super Strength, differ in composition and potency from the tablets comprising Adler's Compound, Standard Strength, whereas all of the tablets are identical in composition and potency.

(e) that distribution of said drug is licensed by the person whose photograph appears on various items of the labeling and who is identified there as Konrad Adler, a German specialist in glandular research, whereas said photograph is in fact that of a professional model who resided in Hollywood, California, years ago, when said photograph was taken.

(16) When the defendants cause the drug, Bio-Glan Male Formula together with Bio-Glan Fortified Wheat Germ Oil, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to this Complaint and incorporated herein:

(a) Exhibit 7—letter from Glandular Products Company purporting [7] to be signed by "John Garwood;"

- (b) Exhibit 8—large testimonial folder;
- (c) Exhibit 9—letter from Glandular Products Company purporting to be signed by “John Garwood, Medical Director;”
- (d) Exhibit 10—small testimonial folder;
- (e) Exhibit 11—folder describing book “Modern Sex Life”;
- (f) Exhibit 12—order form;
- (g) Exhibit 13—letter from Glandular Products Company marked “Confidential” and purporting to be signed by “John Garwood”;
- (h) Exhibit 14—folder entitled “New Safe Bio-Glan Male Formula”;
- (i) Exhibit 15a—bottle label for Bio-Glan Male Formula, Regular Strength, and bottle label for Bio-Glan Fortified Wheat Germ Oil;
- (j) Exhibit 15b—bottle label for Bio-Glan Male Formula, Double Strength, and bottle label for Bio-Glan Fortified Wheat Germ Oil.

(17) Defendants violate Section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction and delivery for introduction into interstate commerce of the drug, Bio-Glan Male Formula together with Bio-Glan Fortified Wheat Germ Oil, with labeling as described in paragraph (16) above, which is misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading since it represents, suggests,

and creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence whereas it is not efficacious for such purposes;

(b) that said drug is marketed by Glandular Products Company upon the advice and guidance of a Medical Director, John Garwood, whereas said Company has no Medical Director and the name "John Garwood" is a fictitious one adopted by Wayne A. Parkinson, who is not trained in the field of medicine;

(c) that the tablets comprising Bio-Glan Male Formula, Double Strength, have twice the potency of the tablets comprising Bio-Glan Male Formula, Regular Strength, whereas all of the tablets are identical in composition [8] and potency; and

(d) that the use of the Bio-Glan Male Formula, Double Strength, creates such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of a double-strength anaesthetic ointment to retard the male sexual climax, whereas the use of said drug will not cause any sexual rejuvenation.

(18) When the defendants cause the drug, Vita-Glan Male Formula, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to this Complaint and incorporated herein:

(a) Exhibit 16—folder entitled “Amazing New Vita-Glan”;

(b) Exhibit 17—folder entitled “A Report to Physicians and the Public”;

(c) Exhibit 18—order form;

(d) Exhibit 19a—bottle label for Vita-Glan Male Formula, Regular Strength;

Exhibit 19b—bottle label for Vita-Glan Male Formula, Double Strength.

(19) Defendants violate Section 301(a) of the Act [21 U.S.C. 331(a)] by causing the introduction and delivery for introduction into interstate commerce of the drug, Vita-Glan Male Formula, with labeling as described in paragraph (18) above, which is misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] in that the labeling is false and misleading since it represents, suggests, and creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence whereas it is not efficacious for such purposes;

(b) that said drug is highly efficacious in overcoming nervousness, loss of muscle tone, vague aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, and mental dullness, whereas it is not efficacious for such purposes. [9]

(c) that said drug is marketed by Glandular Products Company upon the advice and guidance of a Medical Director, whereas said Company has no Medical Director;

(d) That the tablets comprising Vita-Glan Male Formula, Double Strength, have twice the potency of the tablets comprising Vita-Glan Male Formula, Regular Strength, whereas all of the tablets are identical in composition and potency;

(e) that the use of the Vita-Glan Male Formula, Double Strength, creates such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of an anaesthetic ointment to retard the male sexual climax, whereas the use of said drug will not cause any sexual rejuvenation.

(20) Plaintiff is informed and believes that if the defendants are forced by an injunction to discontinue their offensive labeling they will, unless further enjoined, continue the promotion and distribution of the aforesaid drugs and similar drugs by making claims for sexual rejuvenation through collateral media outside of labeling. In that case, the drugs would be misbranded within the meaning of 21 U.S.C. 352(f)(1) in that their labeling would fail to bear adequate directions for use.

(21) Plaintiff is informed and believes that, unless restrained by this Court, the defendants will continue to introduce and deliver for introduction into interstate commerce the aforesaid drugs and similar drugs and other drugs offered for similar

purposes which are misbranded within the meaning of 21 U.S.C. 352(a) or 352(f)(1).

Wherefore, plaintiff prays:

That the defendants and each of their agents, servants, employees, and attorneys, and all persons in active concert or participation with any of them, be perpetually enjoined from directly or indirectly causing to be introduced or delivered for introduction into interstate commerce, in violation of Section 301(a) of the Act [21 U.S.C. 331(a)] the drugs hereinbefore described or any similar drugs or any other drugs offered for similar purposes which are misbranded within the meaning of Sections 502(a) or 502(f)(1) of the Act [21 U.S.C. 352(a) or 352(f)(1)]; and [10]

That a Temporary Restraining Order be granted without notice to the defendants restraining the defendants as prayed hereinabove since, as shown by the attached affidavits, immediate and irreparable loss and damage will result to the plaintiff before notice can be served and a hearing had thereon; and

That at the earliest possible time during the effectiveness of the Temporary Restraining Order, an order be made and entered directing the defendants to show cause, at a time and place to be designated in such order, why they should not be restrained as herein prayed during the pendency of this action; and that upon the hearing of said order to show cause, a Preliminary Injunction be granted restrain-

ing the defendants as herein prayed during the pendency of this action; and

That the defendants be ordered to tender to all present and past purchasers of the drugs enumerated in paragraph (2) above, a refund of all amounts collected by said defendants from said purchasers; and

That the plaintiff be given judgment for its costs herein and for such other and further relief as to the Court may seem just and proper.

LAUGHLIN E. WATERS,
United States Attorney,

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Chief, Civil Division.

Duly Verified.

[Endorsed]: Filed February 26, 1954. [11]

[Title of District Court and Cause.]

AFFIDAVITS IN SUPPORT OF PRAYER
FOR TEMPORARY RESTRAINING ORDER

Attached are the affidavits of:

1. Gordon R. Wood, Chief, Los Angeles District, Food and Drug Administration, Department of Health, Education, and Welfare.
2. Dr. Homer C. Lawson, M.D., Pharmacologist.
3. Dr. Carl E. Ebert, M.D., Urologist.

4. Dr. James Edward McGinnis, M.D., Psychiatrist.
5. Dick Whittington, Photographer.
6. Winifred Westrem.

LAUGHLIN E. WATERS,
United States Attorney,

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney.

United States of America,
Southern District of California—ss.
State of California,
County of Los Angeles.

AFFIDAVIT OF GORDON R. WOOD

Gordon R. Wood, being first duly sworn, deposes and says that he is Chief, Los Angeles District, Food and Drug Administration, Department of Health, Education, and Welfare, and that the following facts, which are supplemental to those stated in the verified Complaint for Injunction filed in the above proceeding, appear from the official records of the Food and Drug Administration in his custody, and from official investigations and reports made under his direction by inspectors of the said Los Angeles District:

(1) With respect to the drug "Adler's Compound," wherein the sales promotional material was

mailed from London, England, over 150,000 of the mailing envelopes and over 150,000 of the airmail business reply envelopes were printed in Los Angeles, California. These envelopes are identified in the Complaint for Injunction as Exhibits 1 and 5.

(2) In preparing the German letterhead, the artwork, and the remaining layout for the form letter identified in the Complaint for Injunction as Exhibit 2, the Los Angeles firm, which printed the aforesaid envelopes, received from the defendants English language copy, material parts of which the printing firm then translated into the German language at the request of the defendants.

(3) In response to the mail-order solicitation described in paragraph (12) of the Complaint for Injunction, defendants have received hundreds of orders per week for Adler's Compound, each order, according to the order form, ranging in amount from \$10 to \$35.

(4) Defendants thus far have had a total of over 400,000 tablets of the drug they designate "Adler's Compound" manufactured for them in Los Angeles, California. Approximately 200,000 of these tablets were delivered to defendants by the manufacturer on February 19, 1954. Sixty tablets of this composition, which defendants sell for \$10 per bottle, can be purchased in wholesale [37] quantities for approximately 25 cents.

(5) Defendants are in the midst of distributing in interstate commerce a large quantity of Adler's

Compound and the other drugs enumerated in paragraph (2) of the Complaint for Injunction. Defendants are thereby now causing immediate and irreparable loss and damage to the public since, for the reasons stated in the medical affidavits which accompany this affidavit, said drugs are worthless for the purposes for which they are offered, and since large numbers of purchasers throughout the nation are being induced to order and pay for the drugs.

/s/ GORDON R. WOOD.

Subscribed and sworn to before me this 26th day of February, 1954.

[Seal] EDMUND L. SMITH,
Clerk, U. S. District Court, Southern District of
California.

By /s/ [Indistinguishable],
Deputy. [38]

United States of America,
Southern District of California—ss.
State of California,
County of Los Angeles.

AFFIDAVIT OF HOMER C. LAWSON, M.D.

Homer C. Lawson, M.D., having been first duly sworn, deposes and says:

(1) I am a Doctor of Medicine having received that degree from the University of Nebraska Medical School in 1928.

(2) I engaged in the general practice of medicine for twelve years following receipt of the degree of Doctor of Medicine.

(3) Since 1941 I have specialized in the study of Pharmacology.

(4) Pharmacology is the study of the action of drugs and related substances in man and other animals.

(5) I have been affiliated with the Department of Pharmacology of the University of Southern California Medical School since 1941.

(6) I am now, and have for some time been, a professor of Pharmacology in the Department of Pharmacology at the University of Southern California Medical School.

(7) I have been shown a statement of composition, labels, and labeling of the preparations designated as "Adler's Compound," "Bio-Glan Male Formula," "Bio-Glan Fortified Wheat Germ Oil," and "Vita-Glan Male Formula" distributed by Glandular Products Company, Long Beach, California.

(8) "Adler's Compound" appears to be offered as a treatment for male sexual weakness and impotence.

(9) The preparation "Adler's Compound" consists of several inert glandular ingredients which have no physiological activity and very small quantities of minerals and vitamins, together with a very small amount of caffeine.

(10) The preparation "Adler's Compound" has no value whatever in the treatment of male sexual weakness or impotence.

(11) The psychosomatic treatment of male sexual weakness of psychogenic origin cannot be effected by the administration of any drug because the treatment [39] of impotence or male sexual weakness of psychogenic origin involves a search for underlying psychiatric factors and their correction by recognized psychotherapeutic procedures.

(12) The preparation "Bio-Glan Male Formula" also is offered for the treatment of male sexual weakness and impotence. This preparation consists of a mixture of three B vitamins (Vitamin B₁, Vitamin B₂ and Niacinamide) in an inert glandular base which would have no therapeutic value.

(13) There is no medical basis for supposing that male sexual weakness or impotence of psychosomatic origin is due to a deficiency of the B vitamins contained in "Bio-Glan Male Formula."

(14) The administration of a preparation of the composition of "Bio-Glan Male Formula" in either "regular strength" with fortified wheat germ oil, or "double strength" with fortified wheat germ oil would be of no value in the treatment of male sexual weakness or impotence, for the reasons stated in paragraph (11) above.

(15) The preparation "Vita-Glan Male Formula" is of the same composition as "Bio-Glan Male Formula."

(16) "Vita-Glan Male Formula" is offered for male sexual weakness and impotence.

(17) The preparation "Vita-Glan Male Formula" would be of no value in the treatment of male sexual weakness or impotence for the reasons stated in paragraph (11) above.

(18) Distribution of the drugs, "Vita-Glan Male Formula," "Bio-Glan Male Formula," and "Adler's Compound" as a treatment for male sexual weakness or impotence constitutes a deception of the purchaser, since none of these articles is of any value in the treatment of such conditions.

(19) It is the consensus of well-informed physicians and pharmacologists [40] that there is no drug or combination of drugs which constitutes adequate treatment for male sexual weakness or impotence.

/s/ HOMER C. LAWSON.

Subscribed and sworn to before me this 24th day of February, 1954.

/s/ RALPH W. WEILERSTEIN,

Employee of the Department of Health, Education, and Welfare, designated under the Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940, and Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits. [41]

United States of America,
Southern District of California—ss.
State of California,
County of Los Angeles.

AFFIDAVIT OF CARL E. EBERT, M.D.

Carl E. Ebert, M.D., having been first duly sworn,
deposes and says:

(1) I am a licensed physician in the State of California with a degree of Doctor of Medicine.

(2) I have done postgraduate work in Urology.

(3) I have specialized in the practice of Urology, and I am a Diplomate of the American Board of Urology. I have offices at 1893 Wilshire Boulevard, Los Angeles, California.

(4) Urology is that branch of medicine that deals with the male urinary and genital system and the female urinary system.

(5) I have been shown a statement of composition, the labels, and the labeling of the drugs, "Adler's Compound," "Bio-Glan Male Formula" and "Bio-Glan Fortified Wheat Germ Oil," and "Vita-Glan Male Formula."

(6) It appears that these articles are all offered for the treatment of male sexual weakness and impotence.

(7) Male sexual weakness and impotence may be due to many factors, most of which are not capable of being recognized by the person who suffers from

them. Some of these factors may be the result of serious physical disorders, while others may be due to psychological factors.

(8) The treatment of impotence and male sexual weakness due to physical disorders consists of determining the cause and correcting it.

(9) The treatment of impotence and male sexual weakness due to psychological factors consists of determining what the psychological cause is and correcting it.

(10) The administration of preparations such as these which contain small quantities of B vitamins, inert glandular extracts with or without the addition of minerals or wheat germ oil, does not constitute a proper treatment [42] of any form of male sexual weakness or impotence.

(11) The promotion of articles such as "Adler's Compound," "Bio-Glan Male Formula," together with "Bio-Glan Fortified Wheat Germ Oil," and "Vita-Glan Male Formula" plays on the desire of persons suffering from a variety of conditions ranging from boredom to severe psychiatric and physical illness for a magical cure of their underlying disorders.

(12) Distribution of these drugs for this purpose constitutes a deception upon the prospective purchaser, since they neither uncover the cause nor treat, in any proper manner, the conditions for which they are offered.

(13) It is the consensus of well informed physicians that there is no drug or combination of drugs which constitutes an adequate treatment for male sexual weakness or impotence.

/s/ CARL E. EBERT, M.D.

Subscribed and sworn to before me this 24th day of February, 1954.

/s/ RALPH W. WEILERSTEIN,
Employee of the Department of Health, Education,
and Welfare, designated under the Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940, and Reorganization Plan No. I of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits. [43]

United States of America,
Southern District of California—ss.
State of California,
County of Los Angeles.

AFFIDAVIT OF
JAMES EDWARD MCGINNIS, M.D.

James Edward McGinnis, having been first duly sworn, deposes and says:

(1) I am a licensed physician in the State of California with a degree of Doctor of Medicine from Stanford University, in 1938.

(2) I did graduate work in psychiatry and neurology at Stanford Hospital and Los Angeles County General Hospital.

(3) I have specialized in the practice of psychiatry and neurology since 1938.

(4) I have been consulting psychiatrist for the California Vocational Institution and a medical examiner for the Superior Court of the State of California.

(5) Psychiatry is that branch of medicine that deals with disorders affecting the personality and interpersonal relationships.

(6) I am Assistant Clinical Professor of Psychiatry at the University of Southern California Medical School.

(7) I am a member of the American Medical Association and a Fellow of the American Psychiatric Association.

(8) I am Chief Psychiatrist Training at the Los Angeles County General Hospital.

(9) I have maintain offices for the private practice of psychiatry at 727 West Seventh Street, Los Angeles.

(10) I have been shown the formula and statement of composition for the preparations designated as Adler's Compound, Bio-Glan Male Formula and Bio-Glan Fortified Wheat Germ Oil, and Vita-Glan Male Formula distributed by Glandular Products Company, Long Beach, California.

(11) I have been shown the labels and labeling for the preparations mentioned in Paragraph (10) above and understand that these preparations are

offered for their psychosomatic value in male sexual weakness of a psychogenic origin. [44]

(12) Male sexual weakness or impotence of psychogenic origin may be due to poor interpersonal relationships, or mental disorders of various types including psychoneuroses and psychoses.

(13) The differential diagnosis of the type of personality disorder, psychological maladjustment, psychoneurosis, or psychosis responsible for male sexual weakness or impotence requires the study of the patient by a physician especially trained in understanding the diagnosis and treatment of such conditions.

(14) The proper and successful treatment of such conditions depends on the proper management of the patient, which includes a careful diagnostic approach and therapy designed to eliminate or reduce the intensity of the causative factors. This therapy is usually psychological or psychiatric in character and does not involve the use of drugs such as are present in the preparations listed in paragraph (10) above.

(15) The use of such preparations as are listed in paragraph (10) above in psychosomatic therapy is based on a misconception of the proper diagnosis or treatment of psychosomatic disorders.

(16) The value of such preparations as are listed in paragraph (10) above for the treatment of male sexual weakness consists primarily of the suggestion to the patient that the article will be of benefit. Such

suggestive therapy is at best only of transient duration, primarily in suggestible individuals.

(17) The promotion and sale of such preparations as are listed in Paragraph (10) above does not constitute psychosomatic therapy, does not possess psychosomatic value, and does not provide any real therapeutic value for male sexual weakness or impotence of psychogenic origin, nor does it constitute proper therapy for any type of male sexual weakness or impotence with which I am acquainted.

(18) It is the consensus of informed experts in the field of psychiatry that the promotion and sale of drugs such as Vita-Glan Male Formula, Bio-Glan Male Formula and Bio-Glan Fortified Wheat Germ Oil, and Adler's Compound are of no psychosomatic value, have no place in [45] psychotherapy, and are definitely not indicated in the treatment of male sexual weakness of psychogenic origin or in any condition stemming therefrom.

/s/ JAMES E. MCGINNIS, M.D.

Subscribed and sworn to before me this 24th day of February, 1954.

/s/ RALPH W. WEILERSTEIN,
Employee of the Department of Health, Education,
and Welfare, designated under the Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940, and Reorganization Plan No. I of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits. [46]

AFFIDAVIT

Sample No. Inv. 86-694L

State of California,
County of Los Angeles.

Before me, Frank McKinlay, an employee of the Department of Health, Education, and Welfare, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803, (5 U.S.C. 521); Reorganization No. IV, Secs. 12-15, effective June 30, 1940; and Reorganization Plan No. 1, of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits, personally appeared Dick Whittington in the county and State aforesaid, who, being first duly sworn, deposes and says:

That 8-inch by 10-inch photograph, of James Carlisle of 2180 North Highland Avenue, Los Angeles, California, was obtained by Inspector Frank McKinlay of the United States Food and Drug Administration on February 24th, 1954, for official Government use;

That the aforesaid photograph is a "Photo by 'Dick' Whittington," posed by a professional model (James Carlisle), and our records show that our firm took it during February, 1941;

That another such print from this same negative was sold under our license, on or about December

9, 1953, to Kellaway Ida Company, 1118 East 8th St., Los Angeles, California.

That Inspector Frank McKinlay paid us the sum of \$10.00 in payment for the copy, 8-inch by 10-inch print, which he obtained from us;

That Inspector Frank McKinlay compared the aforesaid print with 5"x7" negative, in our file, of the photograph.

Print identified as our

File: H126

No. D2-57-3.

Firm:

DICK WHITTINGTON
PHOTOS,

Per:

/s/ DICK WHITTINGTON,
(Title) Prop.

Subscribed and sworn to before me at Los Angeles, California, this 24th day of February, 1954.

/s/ FRANK McKINLAY,

Employee of the Department of Health, Education, and Welfare designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953. [47]





Photo by Dick Whittington

AFFIDAVIT

Sample No. Inv. 86-694L.

State of California,
County of Los Angeles.

Before me, Frank McKinlay, an employee of the Department of Health, Education, and Welfare, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803, (5 U.S.C. 521); Reorganization No. IV, Secs. 12-15, effective June 30, 1940; and Reorganization Plan No. 1, of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits, personally appeared Winifred Westrem in the county and State aforesaid, who, being first duly sworn, deposes and says:

That James Carlisle, whose photograph Inspector Frank McKinlay showed me today, lived as my tenant for four years at 1937 North Highland Avenue, Los Angeles, California (Hollywood District) and passed away on February 3, 1954; that to my knowledge he never used the name Konrad Adler.

Affiant:

/s/ WINIFRED WESTREM,

Address:

1935 N. Highland Avenue,
Los Angeles 28, California.

Subscribed and sworn to before me at Los Angeles, California, this 24th day of February, 1954.

/s/ FRANK McKINLAY,
Employee of the Department of Health, Education,
and Welfare designated under Act of January
31, 1925, Reorganization Plan IV effective June
30, 1940; and Reorganization Plan No. 1 of
1953, effective April 11, 1953.

[Endorsed]: Filed February 26, 1954. [49]

[Title of District Court and Cause.]

TEMPORARY RESTRAINING ORDER

Plaintiff having filed a verified Complaint for Injunction praying for a temporary restraining order without notice, for a preliminary injunction, and for a permanent injunction; and plaintiff having filed affidavits in support of the prayer for a temporary restraining order without notice; and the Court having considered the Complaint and supporting affidavits; and it appearing that defendants are violating and will continue to violate Section 301(a) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 331(a)] unless restrained by order of this Court; and it appearing that the defendants are causing immediate and irreparable loss and damage to the public through their nationwide present and threatened distribution of drugs, misbranded within the meaning of 21 U.S.C. 352(a) or (f)(1), such as

Adler's Compound Standard Strength, [50]

Adler's Compound Super Strength,

Vita-Glan Male Formula, Regular Strength,

Vita-Glan Male Formula, Double Strength,

Bio-Glan Male Formula, Regular Strength,
together with Bio-Glan Fortified Wheat
Germ Oil,

Bio-Glan Male Formula, Double Strength,
together with Bio-Glan Fortified Wheat
Germ Oil,

or other similar drugs, or other drugs offered for similar purposes—namely, for overcoming male sexual weakness and impotence; and it appearing that such drugs are without efficacy for such purposes; and it appearing that a substantial segment of the public in various parts of the United States is being induced to order and pay for such drugs upon defendants' unwarranted representations; and it appearing that the giving of notice to the defendants would unduly delay protecting the public from financial loss and damage caused by defendants' interstate distribution of such misbranded drugs;

It Is Therefore Ordered that the plaintiff's prayer for a temporary restraining order without notice be and it is hereby granted, and that the defendants Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis, and their agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, be and they are hereby temporarily enjoined and restrained from directly or indirectly causing the in-

troducton or delivery for introduction into interstate commerce, of any of the above-enumerated drugs or any other drugs which are misbranded in violation of 21 U.S.C. 352(a) or (f) (1) in that:

(1) the labeling of any such drug represents, suggests or creates the impression in the mind of the prospective purchaser to whom it is directed that such drug is efficacious in overcoming male sexual weakness or impotence; or

(2) the labeling of any such drug fails to bear adequate directions for use by failing to state all of the diseases and conditions of the body for which the drug is intended. [51]

Unless otherwise ordered by this Court, this Order shall expire at 9:15 a.m., March 8, 1954.

Dated: February 26, 1954, at 9:15 a.m.

/s/ BEN HARRISON,

United States District Judge.

[Endorsed]: Filed February 26, 1954. [52]

[Title of District Court and Cause.]

ORDER TO SHOW CAUSE

Upon the Complaint for Injunction and affidavits annexed hereto, and in view of the issuance of a Temporary Restraining Order by this Court on this date, it is this 26th day of February, 1954, by the United States District Court for the Southern District of California, Central Division,

Ordered that the defendants Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis, show cause before this Court in Department 3 at 9:30 a.m., on the 5th day of March, 1954, or as soon thereafter as counsel can be heard, why a preliminary injunction should not issue in this cause as prayed for in said Complaint, provided that copies of this Order and of the said Complaint and affidavits be served on said defendants forthwith but not later than on the 1st day of March, 1954.

/s/ BEN HARRISON,

United States District Judge.

[Endorsed]: Filed February 26, 1954. [53]

[Title of District Court and Cause.]

AFFIDAVIT OF DR. EDWIN W. HIRSCH IN
SUPPORT OF PRELIMINARY INJUNCTION

United States of America,
Southern District of California—ss.
State of Illinois,
County of Cook.

AFFIDAVIT OF EDWIN W. HIRSCH, M.D.

Edwin W. Hirsch, M.D., having been first duly sworn, deposes and says:

(1) I am a licensed physician in the State of Illinois with a degree of Doctor of Medicine from Rush Medical College, Chicago, Illinois, in 1916.

(2) I am a member of the Chicago Medical Society, Illinois State Medical Association, and a Fellow of the American Medical Association.

(3) I am a member of the American Urological Association.

(4) I specialize in the practice of Urology and have offices at 185 North Wabash, Chicago, Illinois.

(5) Urology is that branch of medicine which deals with the diagnosis, treatment, and prevention of diseases in the urinary system and genital system of both males and females.

(6) I have been shown a statement of composition, the labels and the labeling of the drugs "Adler's Compound," "Bio-Glan Male Formula," "Bio-Glan Fortified Wheat Germ Oil," and "Vita-Glan Formula."

(7) I am the author of the book "Modern Sex Life" published by Permabooks, a division of Doubleday and Company, Inc., Garden City, New York, which is pictured in Exhibits 8 and 11 of the Complaint.

(8) The picture purporting to be a photograph of me adjacent to the statement "Dr. Edwin W. Hirsch . . . noted medical doctor, says:", appearing in Exhibits 8 and 10 of the Complaint is not a picture of me.

(9) The photograph attached herewith as Exhibit A is an authentic photograph of me taken in my office, Suite 1314, 185 North Wabash, Chicago,

Illinois, on March 2, 1954, and which I have signed [55] with my name for identification on March 3, 1954.

(10) The statements appearing in said Exhibits 8 and 10, taken out of context of my book "Modern Sex Life," are being used without my knowledge or consent. The unauthorized use of these statements was first brought to my attention on March 2, 1954.

(11) It appears that these articles named in paragraph (6) above are all offered for the treatment of male sexual weakness and impotence.

(12) Male sexual weakness and impotence may be due to many factors, many of which are not capable of being recognized by persons suffering from them. Some of these factors may be the result of serious physical disorders while others may be due to psychological factors such as poor interpersonal relationships, or mental disorders of various types including psychoneuroses and psychoses.

(13) The differential diagnosis of any type of personality disorder, psychological maladjustment, psychoneurosis, or psychosis responsible for male sexual weakness or impotence requires a study of the patient by a physician especially trained in understanding the diagnosis and treatment of such conditions.

(14) The proper and successful treatment of such conditions depends on the proper management of the patient which includes a careful diagnostic approach and therapy designed to eliminate or reduce the intensity of the causative factors.

(15) The administration of preparations such as those listed in paragraph (6) above does not constitute a proper treatment of any form of male sexual weakness or impotence.

(16) The promotion and sale of such preparations as those listed in paragraph (6) above plays on the desire of persons suffering from a variety of conditions and does not constitute proper therapy for any type of male sex weakness or impotence.

(17) Distribution of such drugs for this purpose [56] constitutes a deception upon the prospective purchaser since they neither uncover the cause nor treat in any proper manner the conditions for which they are offered.

(18) It is the consensus of well-informed physicians that there is no drug nor combination of drugs which constitutes adequate treatment for male sexual weakness or impotence.

/s/ EDWIN W. HIRSCH, M.D.

Subscribed and sworn to before me this 3rd day of March, 1954.

/s/ NORMAN DE NOSAQUO,
Employee of the Department of Health, Education,
and Welfare, designated under the Act of January 31, 1925, and Reorganization Plan IV effective June 30, 1940, and Reorganization Plan No. I of 1953, Secs. 1-9, effective April 11, 1953, to administer or take oaths, affirmations, and affidavits. [57]



Endorsed: Filed March 5, 1954.

[Title of District Court and Cause.]

ORDER EXTENDING TEMPORARY
RESTRAINING ORDER

The above entitled matter having come on for hearing this date on an Order to Show Cause why a preliminary injunction should not issue in this cause as prayed for in the Complaint filed herein; and the Court having considered the affidavits and argument offered on behalf of the plaintiff and the defendants; and the Court having ruled that a preliminary injunction should issue after compliance with Local Rule 7(a); and it appearing that the Temporary Restraining Order heretofore issued by this Court in this proceeding will expire on March 8, 1954, at 9:15 a.m., unless extended, and that it is not feasible for this Court to file preliminary findings of fact, preliminary conclusions of law, and a preliminary injunction in accordance with Local Rule 7(a) prior to the expiration date of said Temporary Restraining Order; and for good cause shown as hereinabove specified; [59]

It Is Hereby Ordered that the Temporary Restraining Order heretofore issued by this Court in this proceeding be and it is extended to remain effective unless otherwise ordered by this Court, until 9:15 a.m., March 18, 1954.

Dated: March 5, 1954.

/s/ JAMES M. CARTER,

United States District Judge.

[Endorsed]: Filed March 5, 1954. [60]

[Title of District Court and Cause.]

PRELIMINARY FINDINGS OF FACT AND CONCLUSIONS OF LAW

Preliminary Findings of Fact

(1) Defendant Wayne A. Parkinson trades and does business as Glandular Products Company and Dybutol Company at 1065 and 1067 East Anaheim Street, Long Beach, California.

(2) Defendant Allen H. Parkinson trades and does business as Tide Mailing Service at 1065 and 1067 East Anaheim Street, Long Beach, California. Defendant Margaret M. Willis is the operating manager of said Tide Mailing Service at the afore-said addresses.

(3) Said defendants are the interstate promoters and distributors of articles designated by name as: [61]

(a) Adler's Compound Standard Strength;

(b) Adler's Compound Super Strength;

(c) Vita-Glan Male Formula, Regular Strength;

(d) Vita-Glan Male Formula, Double Strength;

(e) Bio-Glan Male Formula, Regular Strength, together with Bio-Glan Fortified Wheat Germ Oil, and

(f) Bio-Glan Male Formula, Double Strength, together with Bio-Glan Fortified Wheat Germ Oil.

Each of said articles is a drug within the meaning of 21 U.S.C. 321(g) since it is intended for use in the treatment, mitigation, and cure of disease.

(4) The promotion and distribution of said drugs are carried out as a mail-order business conducted in the name of Glandular Products Company and Dybutol Company. These two companies have no employees.

(5) Substantially all of the normal business functions of said companies—including the printing, addressing, and mailing of labeling of the afore-said drugs; the maintenance of extensive mailing lists which defendants have compiled or purchased over a period of years and which include the names and addresses of individuals who have responded in the past to magazine and newspaper advertisements promoting drugs and devices for sexual rejuvenation; the receipt and processing of mail orders for said drugs; the bottling, packaging, and labeling of said drugs; the addressing and shipping of said drugs in response to said mail orders; the maintenance of business records—are performed or arranged for by the Tide Mailing Service.

(6) In the latter part of 1952, said defendants commenced a nationwide mail-order promotion of a drug designated both as Vita-Glan Male Formula, Regular Strength, and Vita-Glan Male Formula,

Double Strength, said drug being offered primarily for sexual rejuvenation. Vita-Glan Male Formula, Regular Strength, and Vita-Glan Male Formula, Double Strength, are identical drugs except that the Double Strength product is recommended in twice the daily dosage of the Regular Strength. Said drug consists of vitamins in an inert glandular base.

(7) In the latter part of 1953, said defendants commenced a [62] nationwide mail-order promotion of a drug designated both as Bio-Glan Male Formula, Regular Strength, and as Bio-Glan Male Formula, Double Strength, alleging its efficacy in sexual rejuvenation. Bio-Glan Male Formula, Regular Strength, and Bio-Glan Male Formula, Double Strength, are identical drugs except that the Double Strength product is recommended in twice the daily dosage of the Regular Strength. The composition of said drug is essentially the same as the aforesaid Vita-Glan Male Formula, except that capsules of wheat germ oil are included in the package.

(8) In the latter part of January, 1954, said defendants initiated a nationwide mail-order promotion of a drug designated both as Adler's Compound Standard Strength, and as Adler's Compound Super Strength. Adler's Compound Standard Strength and Adler's Compound Super Strength are identical drugs except that the Super Strength product is recommended in twice the daily dosage of the Standard Strength. Said drug, which is also offered for sexual rejuvenation, consists of vitamins, minerals, and wheat germ oil in an inert glandular

base. In this current promotion, tens of thousands of persons who are on defendants' mailing list receive letters whose envelopes are postmarked London, England, and give the return address of Konrad Adler & Company, Frankfurt am Main, Germany. Such letters offer the recipient "a new and amazing medical miracle for males," Adler's Compound, which, despite subtle qualification, is represented as a new and secret German formula effective for sexual rejuvenation. European Sales Offices are declared to be located at Paris, Rome and London. Glandular Products Company of Long Beach, California, is stated to be the sole United States distributor of said drug. Enclosed with the letter is a 4-page descriptive folder, an order form, and an airmail business reply envelope on which is imprinted the address of Glandular Products Company. The price range per order is from \$10 to \$35.

(9) All of the drugs distributed by the defendants, including Adler's Compound, are manufactured in the United States.

(10) When the defendants cause the drug, Adler's Compound, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to the [63] Complaint for Injunction:

(a) Exhibit 1—mailing envelope with return address given as "Konrad Adler & Company, Frankfurt am Main, Germany";

(b) Exhibit 2—undated letter bearing letterhead “Konrad Adler & Company” and purported facsimile signature of Konrad Adler;

(c) Exhibit 3—4-page descriptive folder regarding the drug, Adler’s Compound;

(d) Exhibit 4—order form;

(e) Exhibit 5—airmail business reply envelope addressed to Glandular Products Company;

(f) Exhibit 6a—bottle label stating in part “Adler’s Compound Standard Strength”;

Exhibit 6b—bottle label stating in part “Adler’s Compound Super Strength.”

(11) The labeling of Adler’s Compound creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence;

(b) that said drug is manufactured in Germany and is available in the United States in limited supply only;

(c) that said drug is a new and amazing medical miracle developed by outstanding German pharmaceutical knowledge and ingenuity;

(d) that the tablets comprising Adler’s Compound, Super Strength, differ in composition and potency from the tablets comprising Adler’s Compound, Standard Strength; and

(e) that distribution of said drug is licensed by the person whose photograph appears on various items of the labeling and who is identified there as Konrad Adler, a German specialist in glandular research.

(12) The drug, Adler's Compound, is not efficacious in overcoming male sexual weakness or impotence.

(13) Defendants have had a total of over 400,000 tablets of the [64] drug they designate "Adler's Compound" manufactured for them in Los Angeles, California. Approximately 200,000 of these tablets were delivered to defendants by the manufacturer on February 19, 1954. Sixty tablets of this composition, which defendants sell for \$10 per bottle, can be purchased in wholesale quantities for approximately 25 cents. These tablets are available in unlimited supply in the United States.

(14) Adler's Compound is composed of commonly know ingredients and is not a new or amazing medical miracle.

(15) The tablets comprising Adler's Compound Super Strength are identical in composition and potency with the tablets comprising Adler's Compound Standard Strength.

(16) The photograph purporting to be that of Konrad Adler in the labeling of Adler's Compound is in fact that of James Carlisle, a professional model who resided in Hollywood, California, in 1941

when the photograph was taken. Said James Carlisle died on February 3, 1954.

(17) When the defendants cause the drug, Bio-Glan Male Formula together with Bio-Glan Fortified Wheat Germ Oil, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to the Complaint for Injunction:

(a) Exhibit 7—letter from Glandular Products Company purporting to be signed by “John Garwood”;

(b) Exhibit 8—large testimonial folder;

(c) Exhibit 9—letter from Glandular Products Company purporting to be signed by “John Garwood, Medical Director”;

(d) Exhibit-10—small testimonial folder;

(e) Exhibit 11—folder describing book “Modern Sex Life”;

(f) Exhibit 12—order form;

(g) Exhibit 13—letter from Glandular Products Company marked “Confidential” and purporting to be signed by “John Garwood”;

(h) Exhibit 14—folder entitled “New Safe Bio-Glan Male Formula”;

(i) Exhibit 15a—bottle label for Bio-Glan Male Formula, Regular Strength, and bottle label for Bio-Glan Fortified [65] Wheat Germ Oil;

(j) Exhibit 15b—bottle label for Bio-Glan Male Formula, Double Strength, and bottle label for Bio-Glan Fortified Wheat Germ Oil.

(18) The labeling of Bio-Glan Male Formula together with Bio-Glan Fortified Wheat Germ Oil creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence;

(b) that said drug is marketed by Glandular Products Company upon the advice and guidance of a Medical Director, John Garwood;

(c) that the tablets comprising Bio-Glan Male Formula, Double Strength, have twice the potency of the tablets comprising Bio-Glan Male Formula, Regular Strength; and

(d) that the use of the Bio-Glan Male Formula, Double Strength, creates such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of double-strength anaesthetic ointment to retard the male sexual climax.

(19) The drug, Bio-Glan Male Formula together with Bio-Glan Fortified Wheat Germ Oil, is not efficacious in overcoming male sexual weakness or impotence.

(20) Glandular Products Company has no Medical Director, and the name "John Garwood" is a fictitious one adopted by defendant Wayne A. Parkinson who is not trained in the field of medicine.

(21) The tablets comprising Bio-Glan Male Formula, Double Strength, are identical in composition and potency with the tablets comprising Bio-Glan Male Formula, Regular Strength.

(22) The use of Bio-Glan Male Formula will not cause sexual rejuvenation.

(23) When the defendants cause the drug, Vita-Glan Male Formula, to be introduced or delivered for introduction into interstate commerce, the labeling thereof includes the following items which are appended as Exhibits to the [66] Complaint for Injunction:

(a) Exhibit 16—folder entitled “Amazing New Vita-Glan”;

(b) Exhibit 17—folder entitled “A Report to Physicians and the Public”;

(c) Exhibit 18—order form;

(d) Exhibit 19a—bottle label for Vita-Glan Male Formula, Regular Strength;

Exhibit 19b—bottle label for Vita-Glan Male Formula, Double Strength.

(24) The labeling of Vita-Glan Male Formula creates the impression in the mind of the prospective purchaser to whom it is directed

(a) that said drug is highly efficacious in overcoming male sexual weakness and impotence;

(b) that said drug is highly efficacious in overcoming nervousness, loss of muscle tone, vague aches

and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, and mental dullness;

(c) that said drug is marketed by Glandular Products Company upon the advice and guidance of a Medical Director;

(d) that the tablets comprising Vita-Glan Male Formula, Double Strength, have twice the potency of the tablets comprising Vita-Glan Male Formula, Regular Strength; and

(e) that the use of Vita-Glan Male Formula, Double Strength, creates such a rapid sexual rejuvenation in males previously lacking in sexual power as to warrant the use of an anaesthetic ointment to retard the male sexual climax.

(25) The drug, Vita-Glan Male Formula, is not efficacious in overcoming male sexual weakness or impotence.

(26) The drug, Vita-Glan Male Formula, is not efficacious in overcoming any of the conditions specified in paragraph (24) (b) above.

(27) Glandular Products Company has no Medical Director.

(28) The tablets comprising Vita-Glan Male Formula, Double Strength, [67] are identical in composition and potency with the tablets comprising Vita-Glan Male Formula, Regular Strength.

(29) The use of Vita-Glan Male Formula will not cause sexual rejuvenation.

(30) The labeling of each of the aforesaid drugs creates false and misleading impressions as particularized above, within the meaning of 21 U.S.C. 352(a).

(31) Unless restrained by this Court, defendants intend to continue to introduce and deliver for introduction into interstate commerce, with similar false and misleading labeling representations, the aforesaid drugs and similar drugs and other drugs offered for similar purposes.

(32) An injunction which merely restrains the defendants from making false and misleading representations and suggestions in the labeling of the drugs they ship interstate could be circumvented readily by defendants' making representations and suggestions solely in collateral advertising media outside of the labeling, unless defendants are also restrained from using labeling which fails to bear "adequate directions for use," within the meaning of 21 U.S.C. 352(f)(1), by reason of its failure to state all of the purposes and conditions for which the drugs are intended.

(33) Defendants' interstate distribution of the aforesaid drugs is causing large numbers of gullible and credulous persons throughout the country to be deprived of substantial sums of money without receiving anything worthwhile in return, and is therefore causing irreparable loss and damage.

(34) Upon application of the plaintiff, this Court, on February 25, 1954, issued a Temporary

Restraining Order without notice to restrain defendants for 10 days from the interstate shipment of any of said drugs with labeling which creates the impression that such drug is efficacious in overcoming male sexual weakness or impotence, or with labeling which fails to bear adequate directions for use by failing to state all of the diseases and conditions of the body for which it is intended. On March 5, 1954, after hearing the parties on the prayer for a preliminary injunction, this Court issued an Order extending the effectiveness of said Temporary Restraining Order for an additional 10-day period. [68]

(35) The photograph which appears in Exhibits 8, 10, and 14 attached to the Complaint and which purports to be that of Dr. Edwin W. Hirsch, M.D., is not that of said Dr. Hirsch.

(36) The quotations from the book "Modern Sex Life" by said Dr. Hirsch, which appear in Exhibits 8 and 10 attached to the Complaint, are taken out of context, and were used by defendants without the knowledge or consent of Dr. Hirsch. [69]

Preliminary Conclusions of Law

(1) This Court has jurisdiction over the parties and subject matter of this proceeding under 21 U.S.C. 332(a), and is authorized by that provision to restrain violations of 21 U.S.C. 331(a).

(2) Defendants are violating 21 U.S.C. 331(a) by causing misbranded drugs to be introduced and delivered for introduction into interstate commerce.

(3) Said drugs herein involved are misbranded within the meaning of 21 U.S.C. 352(a) in that their labeling is false and misleading in many particulars.

(4) A drug is misbranded within the meaning of 21 U.S.C. 352(f)(1) where its labeling fails to bear "adequate directions for use" by omitting to state the purposes and conditions for which the drug is intended.

(5) Where the Court finds preliminarily that the defendants' interstate distribution of drugs is in violation of law and is causing irreparable loss and damage to large numbers of persons throughout the nation whose interest is represented by the plaintiff, and where the Court is satisfied that the plaintiff will probably establish its case when there is a final determination upon the merits, the Court should issue a preliminary injunction to maintain the status quo.

(6) Plaintiff is entitled to a preliminary injunction restraining the defendants from the interstate shipment of said misbranded drugs during the pendency of this litigation and until the final determination thereof.

Dated: March 11, 1954.

/s/ JAMES M. CARTER,
United States District Judge.

Receipt of Copy acknowledged.

Lodged March 10, 1954.

[Endorsed]: Filed March 11, 1954. [71]

In the United States District Court for the
Southern District of California, Central Division
No. 16415-C

UNITED STATES OF AMERICA,

Plaintiff,

vs.

WAYNE A. PARKINSON, an Individual Trading
and Doing Business as GLANDULAR PROD-
UCTS COMPANY and DYBUTOL COM-
PANY, and ALLEN H. PARKINSON, an
Individual Trading and Doing Business as
TIDE MAILING SERVICE and MAR-
GARET M. WILLIS,

Defendants.

ORDER GRANTING AND DECREE OF PRELIMINARY INJUNCTION

Plaintiff having filed a verified Complaint for In-
junction praying for a temporary restraining order,
a preliminary injunction, and a permanent injunc-
tion; and the Court having issued a Temporary Re-
straining Order; and the defendants having ap-
peared in response to an Order to Show Cause why
a preliminary injunction should not issue; and the
Court having considered the affidavits, briefs, and
arguments offered on behalf of all parties; and the
Court having issued an Order Extending Temporary
Restraining Order; and the Court having filed Pre-
liminary Findings of Fact and Preliminary Con-

clusions of Law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure;

It Is Therefore Ordered that plaintiff's prayer for a preliminary injunction be, and it hereby is, granted, and that the defendants Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis, and each and all of their [72] agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, be and they are hereby preliminarily enjoined and restrained during the pendency of this litigation and until the final determination thereof from doing any of the following acts, directly or indirectly, in violation of Section 301(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(a)] with respect to any of the articles of drug hereinafter enumerated—namely,

Adler's Compound Standard Strength,
Adler's Compound Super Strength,
Vita-Glan Male Formula, Regular Strength,
Vita-Glan Male Formula, Double Strength,
Bio-Glan Male Formula, Regular Strength, together with Bio-Glan Fortified Wheat Germ Oil,
Bio-Glan Male Formula, Double Strength, together with Bio-Glan Fortified Wheat Germ Oil,

or other similar drugs, or other drugs offered for similar purposes, namely, for overcoming male sexual weakness or impotence:

(1) Introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce any such article of drug which is:

(a) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the impression that such article or any of the other articles enumerated above is efficacious in overcoming male sexual weakness or impotence; or

(b) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the impression that such article or any of the other articles enumerated above is efficacious in overcoming nervousness, loss of muscle tone, vague aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, or mental dullness; or

(c) Misbranded within the meaning of Section 502(a) of the Act [73] [21 U.S.C. 352(a)] by reason of any other false or misleading representation in its labeling; or

(d) Misbranded within the meaning of Section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that its labeling does not bear adequate directions for use because it does not contain a statement of all

the purposes and conditions for which the article is intended by the defendants.

It Is Further Ordered that this preliminary injunction shall remain in effect until after final disposition of this cause by the Court after trial on the merits, and until it is expressly dissolved; and

It Is Further Ordered that this Court expressly retain jurisdiction over the subject matter and parties herein in order that it may issue such further Orders and Decrees as may be necessary to the proper disposition of this proceeding.

Dated: March 11, 1954.

/s/ JAMES M. CARTER,

United States District Judge.

Receipt of Copy acknowledged.

Lodged March 10, 1954.

[Endorsed]: Filed March 11, 1954.

Judgment docketed and entered March 11, 1954.

[Title of District Court and Cause.]

NOTICE OF APPEAL

Notice is hereby given that Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis, defendants above named, hereby appeal to the United States Court of Appeals for the Ninth Circuit from the Order Granting and Decree of Preliminary In-

junction docketed and entered in this action on March 11, 1954.

Dated: May 4, 1954.

EDWIN M. ROSENDAHL,

/s/ EDWIN M. ROSENDAHL,

Attorney for Appellants, Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis.

Affidavit of service by mail attached.

[Endorsed]: Filed May 4, 1954. [75]

[Title of District Court and Cause.]

STIPULATION FOR DISMISSAL OF
APPEAL

It is hereby stipulated by and between the parties hereto, through their respective counsel, that the appeal of the defendants in the within matter be dismissed.

The reason for this stipulation is that the defendants have voluntarily agreed to dismiss the appeal, and to limit the litigation herein to other portions of plaintiff's complaint not covered by the appeal.

Dated: July 20, 1954.

LAUGHLIN E. WATERS,
United States Attorney;

MAX F. DEUTZ,

Assistant U. S. Attorney,
Chief of Civil Division,

/s/ MAX F. DEUTZ,

Assistant U. S. Attorney
Attorneys for Plaintiff,

/s/ EDWIN M. ROSENDAHL,

Attorney for all defendants.

Good cause appearing therefor, it is hereby ordered that the appeal of the defendants herein, be dismissed, and that the defendants' bond for costs be, and the same is hereby exonerated.

Dated this 26 day of July, 1954.

/s/ JAMES M. CARTER,

United States District Judge.

[Endorsed]: Filed July 26, 1954. [78]

[Title of District Court and Cause.]

FINAL CONSENT JUDGMENT AS TO
PERMANENT INJUNCTION ONLY

Plaintiff having filed a verified complaint for injunction; and the Court having issued a temporary restraining order, preliminary findings of fact and conclusions of law, and a preliminary injunction; and upon the consent of all parties, before any testimony has been taken, and without any additional finding by the Court on any issue of fact or law;

and without any admission by the defendants regarding the truth of the allegations in the Complaint by reason of the entry of this Final Consent Judgment; it is

I.

Ordered, adjudged, and decreed that this Court has jurisdiction of the subject matter hereof and of all the parties herein; and it is further [79]

II.

Ordered, adjudged, and decreed that the defendants, Wayne A. Parkinson, Allen H. Parkinson, and Margaret M. Willis, and each and all of their agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, be and they are hereby permanently enjoined and restrained from doing any of the following acts, directly or indirectly, in violation of Section 301(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 331(a)] with respect to any of the articles of drug hereinafter enumerated and described—namely,

Name of Drug: Adler's Compound (Standard Strength)

Composition of Drug

Each tablet contains:

Potassium Sulphate	1.5 mg.
Vitamin B1	1.5 mg.
Vitamin C	5.0 mg.
Niacinamide	5.0 mg.
Caffein	0.5 gr.

Molybdenum as present in Sodium

Molybdenate	0.2 mg.
Calcium Pantothenate	2.5 mg.
Vitamin B12	1.5 mg.

Wheat Germ Oil fortified with D-Alpha

Tocopherol Succinate equivalent by
biological assay to 5 International
Units of Vitamin E

The above contents are amalgamated in a base of inert testicular powders, prostate substance, glandular tissue, and other excipients.

Name of Drug: Adler's Compound
(Super Strength)

The composition of each tablet is identical with that of Adler's Compound (Standard Strength) [80]

Name of Drug: Vita-Glan Male Formula
(Regular Strength)

Composition of Drug

Each tablet contains:

Vitamin B ₁	5 mg.
Vitamin B ₂	3.5 mg.
Niacinamide	15 mg.

The above contents are in a base of Orchic, Pancreatin, Prostate, and Adrenal Gland Substances, plus other excipients.

Name of Drug: Vita-Glan Male Formula
(Double Strength)

The composition of each tablet is identical with that of Vita-Glan Male Formula (Regular Strength)

Name of Drug: Bio-Glan Male Formula
(Regular Strength)

The composition of each tablet is identical with that of Vita-Glan Male Formula (Regular Strength)

Name of Drug: Bio-Glan Male Formula
(Double Strength)

The composition of each tablet is identical with that of Vita-Glan Male Formula (Regular Strength)

Name of Drug: Bio-Glan Fortified Wheat Germ Oil

Each perle contains Wheat Germ Oil fortified with d-alpha tocopherol acetate equivalent by biological assay to Five International Units of Vitamin E (with color added to gelatin perle), or other similar drugs, or other drugs offered for similar purposes, namely, for overcoming male sexual weakness or impotence:

(1) Introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce any such article of drug which is:

(a) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling

which conveys the false and misleading impression that such article or any of the other articles described above is efficacious in overcoming male sexual [81] weakness or impotence; or

(b) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the false and misleading impression that such article or any of the other articles described above is efficacious in overcoming nervousness, loss of muscle tone, vague aches and pains, fatigue, irritability, headaches, dizziness, weakness, mental depression, insomnia, digestive upsets, loss of appetite, neuritis, backache, or mental dullness; or

(c) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the false and misleading impression that such article or any of the other articles described above is manufactured in a foreign country only and is available in the United States in limited supply; or

(d) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the false and misleading impression that such article or any of the other articles described above is a new or amazing medical miracle developed by foreign pharmaceutical knowledge and ingenuity; or

(e) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which conveys the false and misleading impression that such article or any of the other articles described above, if designated as "super strength" or "double strength," has a different composition and greater potency than a similar article designated as "standard strength" or "regular strength"; or

(f) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any photograph of a professional model in its labeling which, together with other representations or suggestions, conveys the false and misleading impression that the person who posed for such photograph is a scientist who manufactures, distributes or approves of such article or any of the other articles described above; or

(g) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling [82] which conveys the false and misleading impression that such article or any of the other articles described above is marketed upon the advice and guidance of a non-existing "medical director"; or

(h) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any representation or suggestion in its labeling which creates the false and misleading impression that the use of such article or of any of the other articles described above creates such a rapid sexual

rejuvenation in males previously lacking in sexual power as to warrant the use of an anaesthetic ointment to retard the male sexual climax; or

(i) Misbranded within the meaning of Section 502(a) of the Act [21 U.S.C. 352(a)] by reason of any other false or misleading representation or suggestion in its labeling; or

(j) Misbranded within the meaning of Section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] in that its labeling does not bear adequate directions for use because it does not state all of the purposes and conditions for which the article is intended; and it is further

III.

Ordered, Adjudged, and Decreed that each of said defendants shall call this Final Consent Judgment to the attention of all of his or her agents, employees, servants, or distributors who now or hereafter sell or offer for sale or otherwise assist in marketing any of the articles of drug described above, and shall require each such person to sign a written statement that he or she has read this Judgment; and said defendants shall maintain a file of such statements and permit a duly authorized representative of the Department of Health, Education, and Welfare, at any reasonable time, to have access to them and to copy them; and it is further

IV.

Ordered, Adjudged, and Decreed that jurisdiction of this Court is retained for the purpose of enabling

any of the parties to this Judgment to apply at any time for such further orders and directions as may be necessary or [83] appropriate for the construction or carrying out of this Judgment or for modification of any of the provisions thereof and for the purpose of enforcing compliance therewith and the punishment of violations thereof; nor shall anything herein prejudice the right of any party to move the Court for modification of this Judgment in the event of changed conditions of law, fact, or scientific opinion; and it is further

V.

Ordered, Adjudged, and Decreed that only a violation of Part II of this Judgment shall constitute a violation of the Federal Food, Drug, and Cosmetic Act within the meaning of 21 U.S.C. 332(b); and it is further

VI.

Ordered, Adjudged, and Decreed that the question of restitution is specifically reserved and is not a part of this Judgment, and that said question shall be subject to subsequent determination by this Court; and it is further

VII.

Determined, pursuant to Civil Rule 54(b), that while this Judgment does not adjudicate all of the claims for relief presented in this action, there is no just reason for delay in entering this Judgment; and it is further

VIII.

Directed that this Judgment shall be entered forthwith.

Dated: November 5, 1954.

/s/ JAMES M. CARTER,
United States District Judge.

We hereby consent to the entry of the foregoing Judgment and we each [84] acknowledge receipt of a copy thereof.

LAUGHLIN E. WATERS,
United States Attorney,

/s/ MAX F. DEUTZ, **J.L.B.**
Assistant United States Attorney, Chief of Civil
Division, Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,
/s/ EDWIN M. ROSENDAHL,
Attorneys for Defendants.

/s/ WAYNE A. PARKINSON,
/s/ ALLEN H. PARKINSON,
/s/ MARGARET M. WILLIS,
Defendants.

[Endorsed]: Filed November 5, 1954.

Docketed and entered November 5, 1954. [85]

[Title of District Court and Cause.]

STIPULATION AND ORDER RE ISSUE OF RESTITUTION

This Court having approved and entered a "Final Consent Judgment as to Permanent Injunction Only" which adjudicates most of the issues in this case; the parties to this proceeding, through their respective counsel, hereby stipulate as follows subject to the approval of the Court:

(1) The only dispute between the parties which the parties themselves cannot resolve relates to the plaintiff's prayer for restitution as stated in the penultimate paragraph of the Complaint for Injunction.

(2) This dispute may be divided into two parts—namely,

(a) Does the District Court in this case have discretionary power, ancillary to its jurisdiction to grant injunctive relief under 21 U.S.C. 332(a), to compel a defendant who has sold drugs in violation of the Federal Food, Drug and Cosmetic Act, to tender a refund of the purchase money to [86] customers who have bought those drugs?

(b) If it is within the Court's jurisdiction to issue an order of restitution, should it issue such an order in this case?

(3) For the purpose of deciding the issue stated in paragraph (2)(a) only, all of the allegations of the Complaint for Injunction, as well as the con-

tents of and exhibits attached to the affidavits filed on behalf of the plaintiff, are true. Defendants retain the right to object to the consideration by the Court of any facts alleged in the Complaint or appearing in any other documents or exhibits on the ground that they are irrelevant or should not be considered by the Court in deciding the issue stated in paragraph (2)(a).

(4) The issue stated in paragraph (2)(a) involves a significant question of first impression in food and drug cases. The parties propose that this issue be briefed and argued in accordance with the following schedule:

January 4, 1955—Plaintiff's brief due.

February 28, 1955—Defendants' brief due.

March 28, 1955—Plaintiff's reply brief due.

April, 1955—Oral argument to be set in April.

(5) If the issue stated in paragraph (2)(a) is resolved in favor of the plaintiff, the parties will take all steps necessary to facilitate a decision with respect to the issue stated above in paragraph (2)(b), by bringing all facts pertinent to that issue before the Court as expeditiously as possible.

Dated: November 5th, 1954.

LAUGHLIN E. WATERS,

United States Attorney,

/s/ MAX F. DEUTZ,

J.L.B.

Assistant United States Attorney, Attorneys for Plaintiff.

/s/ EUGENE M. ELSON,

/s/ EDWIN M. ROSENDAHL,
Attorneys for Defendants.

It Is So Ordered this 5th day of November, 1954.

/s/ JAMES M. CARTER,
United States District Judge.

[Endorsed]: Filed November 5, 1954.

Docketed and entered November 5, 1954. [88]

[Title of District Court and Cause.]

MINUTES OF THE COURT—JULY 25, 1955

Hon. James M. Carter, District Judge.

Proceedings:

For separate trial on the issue of restitution only, pursuant to the provisions of the decree entered herein Nov. 5, 1954.

Court makes a statement, and it is stipulated and ordered that the proceedings today will be limited to separate trial on the question of whether the Court has jurisdiction in its discretion to require restitution, leaving for another time the further separate trial and determination of whether such restitution should be granted, if the Court determines after today's proceedings that it has such jurisdiction.

Attorney Deutz argues to the Court for government.

Attorney Elson argues to the Court for defendants.

It Is Ordered that the cause stand Submitted on said issue.

JOHN A. CHILDRESS,
Clerk;

By /s/ L. B. FIGG,
Deputy Clerk. [89]

[Title of District Court and Cause.]

OPINION

Appearances:

LAUGHLIN E. WATERS,
United States Attorney;
MAX DEUTZ,
Asst. United States Attorney,
Attorneys for Plaintiff.

EUGENE M. ELSON,
Attorney for Defendant. [90]

This case poses the question as to whether the district court has power to order restitution in an injunction proceeding under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. 331-392; Act of June 25, 1938, Chap. 675, 52 Stat. 1040].

The case is one of first impression under the Food and Drug laws, although the problem has been discussed recently in law reviews and journals.¹

The matter was heretofore heard on an application for a preliminary injunction, and a decree of preliminary injunction was made and entered March 11, 1954. Thereafter a final consent judgment, as to permanent injunction only, was made and entered on November 5, 1954.

The complaint, in addition to praying for general injunctive relief, prayed "that the defendants be ordered to tender to all present and past purchasers of the drugs enumerated * * * a refund of all amounts collected by said defendants from said purchasers." By stipulation of the parties, the question is presented as to whether the district court had discretionary power, ancillary to its jurisdiction to grant injunctive relief under 21 U.S.C.A. 332(a), to compel the defendants to refund to purchasers the money paid for the drugs involved in the action, and whether the court has jurisdiction to issue such an order. The question as to whether the court should exercise this power, if it possesses it, is reserved by the stipulation for further hearing if necessary.

21 U.S.C.A. Sec. 332(a) reads:

"Injunction proceedings — Jurisdiction of courts (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause

shown, and subject to the provisions of Sec. 381 (relating [91] to notice to opposite party) of Title 28, as amended, to restrain violations of section 331 of this title, except paragraphs (e), (f), and (h)-(j). [Act of June 25, 1938, chap. 675, Sec. 302, 52 Stat. 1043]”

We are not concerned with the exceptions.

We start with the axiomatic premise that the district court is one of limited jurisdiction, and has only the power and the jurisdiction spelled out in the statutory enactments of Congress. We exclude from consideration the general equity power of the court called into play in a diversity suit, and also exclude those situations in which, by statute, the Congress has expressly provided that the court may exercise all the powers of a court of equity. We also exclude from consideration the power of a district court to compel compliance with its orders when violated or threatened to be violated, (*McComb v. Jacksonville Paper Co.* [1949] 336 U.S. 187, 193). Sec. 332(b) 21 U.S.C.A., expressly makes reference to a violation of the injunction, and proceedings thereon.

The plaintiffs predicate their argument on analogy to (a) the Rent and Price Control cases, (b) Fair Labor Standard cases, and (c) the Anti-trust cases.

1.

The Rent Control cases.

In *Porter v. Warner Holding Co.* [1946] 328 U.S. 395, the trial court and the court of appeals both held there was no jurisdiction under the statute to order restitution. The Supreme Court reversed. The statute involved was Sec. 205(a) of the Emergency Price Control Act of 1942, 50 U.S.C.A. App., Sec. 925(a) [56 Stat. 23, 33]. It provided that the administrator might apply to the appropriate court * * * “for an order enjoining such acts or practices, or for an order [92] enforcing compliance with such provision, and upon a showing by the Administrator that such person has engaged or is about to engage in any such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond.” [Emphasis added.]

Sec. 205(a) of the Emergency Price Control Act of 1942 [50 U.S.C.A. App. Sec. 925(a)] first reached the Supreme Court in *Hecht Co. v. Bowles* [1944] 321 U.S. 321. The Supreme Court held that the court could, under the statutory language involved, fashion an appropriate decree to obtain compliance, and at page 328, said:

“It seems apparent on the face of § 205(a) that there is some room for the exercise of discretion on the part of the court * * * Though the Administrator asks for an injunction, some ‘other order’ might be more appropriate * * * Such an order, moreover, would seem to be a

type of 'other order' which a faithful reading of § 205(a) would permit a court to issue in a compliance proceeding."

In the Warner Holding case (*supra*) the Supreme Court, in reversing, rested jurisdiction to issue a mandatory restitution order on two theories, (1) "as an equitable adjunct to an injunction decree" and (2) "as an order appropriate and necessary to enforce compliance with the Act." (p. 399-400). It said at page 399:

"As recognized in *Hecht v. Bowles* * * * the term 'other order' contemplates a remedy other than that of injunction or restraining order, a remedy entered in the exercise of the District Court's equitable discretion." [93]

Both the *Hecht Co.* case, (*supra*) and the Warner Holding Co. case, (*supra*) considered legislative history of the statute and Sen. Rep. 931, 77th Cong. 2d Session.²

A portion of the report, quoted in the Warner Holding Co. case, (*supra*) read, "Such courts are given jurisdiction to issue whatever order to enforce compliance is proper in the circumstances of each particular case." (p. 401).

Subsequently, the Supreme Court in *U.S. v. Moore* [1951] 340 U.S. 616, referring to its decision in *Porter v. Warner Holding Co.* (*supra*), stated, page 619-620:

"This Court reversed, concluding that an order of restitution was a proper 'other order.' This

interpretation was required to give effect to the congressional purpose to authorize whatever order within the inherent equitable power of the District Court may be considered appropriate and necessary to enforce compliance with the Act * * *

“Adhering to the broad ground of interpretation of the ‘other orders’ provision adopted in the Warner case, we think the order for restitution entered by the District Court in this section was permissible under Section 206(b).”³

We are constrained to believe that *Porter v. Warner Holding Co.* (supra) is authority upon the second proposition, namely that a district court had power to grant an order appropriate and necessary to enforce compliance with the Act, based upon the particular wording of the statute. The other ground was not necessary for the decision. Although considered as dicta, it bears great weight, nevertheless we do not believe that the holding of the Warner case should be so extended. [94]

Since the statute in the case at bar does not contain the reference to “an order enforcing compliance” or “other order” we do not consider the rent cases as decisive of our problem.

2.

The Fair Labor Standards cases.

The Fair Labor Standards Act [29 U.S.C.A. Sec. 201-219] and the Federal Food, Drug, and Cosmetic

Act [21 U.S.C.A. Sections 301-392] were enacted on the same day. [June 25, 1938, 52 Stat. 1060 and 1040 respectively.] Both statutes contained provisions for equitable relief that were almost identical.⁴

Several appellate court cases ruled that restitution of back pay could properly be ordered as an adjunct to an injunction under Section 17 of the Fair Labor Standards Act, [Sec. 217 U.S.C.A. Title 29] which required the rehiring of a discharged employee. *McComb v. Frank Scerbo & Sons*, 177 F. 2d 137, 138-139 (C.A. 2, 1949); *Walling v. O'Grady*, 146 F. 2d 422, 423 (C.A. 2, 1949). Cf. *Walling v. Miller*, 138 F. 2d 629 (C.A. 8, 1943) which held that the district court had power to embody a restitution order in a consent decree.

The Supreme Court however, never ruled on the question expressly, leaving it open in *McComb v. Jacksonville Paper Co.* [1949] 336 U.S. 187-193.

But Congress, concerned with the appellate courts' interpretations of Sec. 17 of the Fair Labor Standards Act [Sec. 217, U.S.C.A. Title 29] amended the section to provide in express terms that restitution was not authorized under the section, [Act of Oct. 26, 1949, Chap. 736, Sec. 15, 63 Stat. 919] and other statutory provisions were enacted relating to restitution suits.⁵

This blunt repudiation by Congress of the asserted powers of a district court to order restitution under Fair [95] Labor Standards Act, with its almost identical provision to that of Sec. 302(a) of the Food and Drug Act [Sec. 332(a) U.S.C.A. Title

21], is significant and convincing insofar as this court is concerned.

3.

The Antitrust cases.

The government also relies for authority on the injunction suits to restrain violations of the Sherman Act, [15 U.S.C.A. Sec. 4] where the courts have sustained the remedy of divestiture; and cites *Schine Chain Theatres, Inc., v. United States* [1948] 334 U.S. 110, holding divestiture to be an equitable remedy and comparing it to restitution; and *United States v. Paramount Pictures* [1948] 334 U.S. 131 to the same effect.

We are not convinced. The Sherman Act in Sec. 4 U.S.C.A. Title 15, [Act of July 2, 1890, Chap. 647, Sec. 4, 26 Stat. 209 as amended] provides, "The several district courts of the United States are invested with jurisdiction to prevent and restrain violations of sections 1-7 of this title; and it shall be the duty of the several district attorneys of the United States * * * under the direction of the Attorney General, to institute proceedings in equity to prevent and restrain such violations." [Emphasis added.] This language, read as a whole, clearly empowers the district court with all the remedies of equity. The decisions cited above are then easily understood.

Nor is divestiture as applied by the courts, the equivalent of restitution. Divestiture requires the defendant to sell his offending interest or stock or properties or to divest himself of his holdings. He is deprived of the offending property at a price. [96]

He is not required to restore monies to his competitors by such a decree, though they may, in certain instances, have the remedy of a treble damage suit expressly provided by statute.

Conclusion

There are fundamental differences in purpose between the Rent and Price Control legislation and the Fair Labor Standards Act on the one hand, and the Federal Food, Drug, and Cosmetic Act on the other. They have been well stated by Rhyne, "Penalty through Publicity; FDA's Restitution Gambit, 7 Food, Drug, Cosmetic L.J. 666-680 [1952],

"The payment of prescribed sums of money is the essence and purpose of the Fair Labor Standards Act, and also of rent and price control laws. Effectuation of the policies of these laws requires the payment of proper sums. But the Federal Food, Drug, and Cosmetic Act is not concerned with payment of money. Its purpose, or as much of it as it relevant here, is to prevent misbranding; that purpose can be accomplished by a restraining order."

Restitution, apart from its equitable considerations may also be considered punitive. It is a further method of punishing a defendant in that it requires him to pay over monies in his possession to others. There is a line of authorities that "an injunction is primarily a preventive remedy; it looks to the future rather than to the past. It is not for the purpose of punishing for wrongful acts already committed," High Grade Food Products

Corp. v. United States [8 Cir. 1947] 160 F. 2d 816, and cases cited at page 819; Minneapolis & St. Louis Ry. Co. v. Pacific Gamble Robinson Co. [8 Cir. 1950] 181 F. 2d 812 at 814; American Chicle Co. v. Topps Chewing Gum [2 Cir. 1954] 210 F. 2d 680 at 683. [97]

We conclude that the remedy of restitution is not within the powers of the district court under the statute. The Food, Drug and Cosmetic Act has provided the sanctions of (1) criminal prosecution and punishment of violators [21 U.S.C.A., Sec. 333], (2) seizure of goods shipped in violation of the Act [21 U.S.C., Sec. 334 (a)], and (3) injunctions against further violations [21 U.S.C.A., Sec. 332 (a)]. There is no indication in Congressional history that supports any other sanction or specifically the power to order restitution under the Food, Drug and Cosmetic Act. The contrary was true in the Congressional history of the Emergency Price Control Act.

The government's arguments that such power in a district court are necessary to effect the essential objectives of the Act and to protect the public's pocketbook should be addressed to Congress, not to a district court. The jurisdiction and power of this court stem not from things necessary or desirable, but from Congressional action.

The defendants will submit an order denying plaintiff relief under its prayer for restitution. Pursuant to the stipulation of the parties there remains nothing further to be done in this case. This order denying such relief concludes the case and should therefore be final and appealable. [98]

Footnotes

¹Rhyne, *Penalty Through Publicity: FDA's Restitution Gambit*, 7 Food, Drug, Cosmetic L.J. 666-680 (1952).

Noland, *Section 302(a) of the Federal Food, Drug, and Cosmetic Act: Restitution Re-examined*, 7 Food, Drug, Cosmetic L.J. 373-400 (1952).

Lev, *The Nutrilite Consent Decree*, 7 Food, Drug, Cosmetic L.J. 56, 65-67 (1952).

Developments in the Law—The Federal Food, Drug, and Cosmetic Act, 67 Harv. LR 632, 718-720 (1954).

Levine, *Restitution—A New Enforcement Sanction*, 6 Food, Drug, Cosmetic L.J. 503-514 (1951).

Goodrich, *Modern Application of an Ancient Remedy*, 9 Food, Drug, Cosmetic L.J. 565-572 (1954).

“Restitution in Food and Drug Enforcement,” note in 4 Stan. L. Rev. 519-536 (1952).

²The Hecht case cited page 25, the Warner Holding case page 10 of the report.

³U. S. v. Moore involves section 206(b) of the Housing and Rent Act of 1947 as amended. This section contains the same “other order” language found in Sec. 205(a) of the Emergency Price Control Act of 1942, involved in *Porter v. Warner Holding Co.* (supra).

⁴Section 17 of the Fair Labor Standards Act [52 Stat. 1069]:

“The district courts of the United States and the United States courts of the Territories and possessions shall have jurisdiction, for cause shown, and subject to the provisions of section 20 (relating to notice to opposite party) of the Act entitled, ‘An act to supplement existing laws against unlawful restraints and monopolies, and for other [99] purposes’ approved October 15, 1914, as amended (U.S.C. 1934 edition, title 28, sec. 381), to restrain violations of section 15.”

⁵Section 16(c) [21 U.S.C.A., Section 216(c)] was amended and Congress thereby created a special statutory pattern designed (1) to permit an independent suit by the Administrator to collect back pay on behalf of employees, and (2) to protect employers from double litigation by declaring that the employee's consent to such suit constituted a waiver of the employee's statutory right to sue in his own behalf.

[Endorsed]: Filed October 21, 1955. [100]

In the United States District Court for the Southern District of California, Central Division

No. 16415-C

UNITED STATES OF AMERICA,

Plaintiff,

vs.

WAYNE A. PARKINSON, an Individual Trading and Doing Business as Glandular Products Company and Dybutol Company, and ALLEN H. PARKINSON, an Individual Trading and Doing Business as Tide Mailing Service, and MARGARET M. WILLIS,

Defendants.

FINAL JUDGMENT DENYING PLAINTIFF'S
PRAYER FOR RESTITUTION

All issues in the above-entitled action, except the issue of restitution having heretofore been disposed of by a "Final Consent Judgment as to Permanent

Injunction Only”; and the issue of restitution having been presented to this court in two parts by “Stipulation and Order re Issue of Restitution”—the first part dealing with whether the court has the power to issue an order of restitution in this cause, and the second part dealing with whether the court should exercise such power herein, if it possesses it; and the court having concluded that it is without jurisdiction to issue an order of restitution in this cause, and that, therefore, it is unnecessary [101] that it decide whether it would issue such an order if it had the power to do so, it is

Ordered, Adjudged and Decreed that plaintiff’s prayer in its complaint for injunction “that the defendants be ordered to tender to all present and past purchasers of the drugs enumerated * * * a refund of all amounts collected by said defendants from said purchasers” is hereby denied.

Dated: This 15th day of November, 1955.

/s/ JAMES M. CARTER,

United States District Judge.

Approved as to form:

LAUGHLIN E. WATERS,

United States Attorney;

/s/ MAX F. DEUTZ,

Assistant United States Attorney, Chief of Civil Division.

Docketed and entered November 16, 1955. [102]

[Endorsed]: Filed November 15, 1955.

[Title of District Court and Cause.]

NOTICE OF APPEAL

Notice Is Hereby Given that the United States of America, plaintiff above named, hereby appeals to the United States Court of Appeals for the Ninth Circuit from the Final Judgment Denying Plaintiff's Prayer for Restitution, dated November 15, 1955, and docketed and entered in this action on November 16, 1955.

Dated this 12th day of January, 1956.

LAUGHLIN E. WATERS,
United States Attorney;

MAX F. DEUTZ,
Assistant U. S. Attorney,
Chief of Civil Division;

/s/ MAX F. DEUTZ,
Assistant U. S. Attorney,
Attorneys for Plaintiff.

[Endorsed]: Filed January 12, 1956. [103]

[Title of District Court and Cause.]

CERTIFICATE BY CLERK

I, John A. Childress, Clerk of the United States District Court for the Southern District of California, do hereby certify that the foregoing pages, numbered 1 to 110, inclusive, contain the original:

Complaint;
Affidavit in Support of Prayer for Temporary Restraining Order;
Temporary Restraining Order;
Order to Show Cause;
Affidavit of Dr. Edwin W. Hirsch in Support of Preliminary Injunction;
Order Extending Temporary Restraining Order;
Preliminary Findings of Fact and Conclusions of Law;
Order Granting and Decree of Preliminary Injunction;
Notice of Appeal, filed May 4, 1954;
Stipulation for Dismissal of Appeal;
Final Consent Judgment as to Permanent Injunction Only;
Stipulation and Order re Issue of Restitution;
Opinion;
Final Judgment Denying Plaintiff's Prayer for Restitution;
Notice of Appeal, filed January 12, 1956;
Letter Addressed to Clerk, U. S. District Court;
Designation of Contents of Record on Appeal;
Statement of Points on Which Appellant Intends to Rely;

And a full, true and correct copy of the Minutes of the Court on July 25, 1955; all in the above-entitled cause constitute the transcript of record on appeal to the United States Court of Appeals for the Ninth Circuit in said cause.

I further certify that my fees for preparing the foregoing record amount to \$2.00, which sum has not been paid by appellant.

Witness my hand and the seal of said District Court this 9th day of February, 1956.

[Seal] JOHN A. CHILDRESS,
Clerk;

By /s/ CHARLES E. JONES,
Deputy.

[Endorsed]: No. 15032. United States Court of Appeals for the Ninth Circuit. United States of America, Appellant, vs. Wayne A. Parkinson, an Individual Trading and Doing Business as Glandular Products Company and Dybutol Company, and Allen H. Parkinson, an Individual Trading and Doing Business as Tide Mailing Service, and Margaret M. Willis, Appellees. Transcript of Record. Appeal from the United States District Court for the Southern District of California, Central Division.

Filed February 10, 1956.

/s/ PAUL P. O'BRIEN,

Clerk of the United States Court of Appeals for the Ninth Circuit.

In the United States Circuit Court of Appeals
for the Ninth Circuit
C.A. No. 15032

UNITED STATES OF AMERICA,
Appellant,
vs.

WAYNE A. PARKINSON, an Individual Trading
and Doing Business as Glandular Products
Company and Dybutol Company, and ALLEN
H. PARKINSON, an Individual Trading and
Doing Business as Tide Mailing Service, and
MARGARET M. WILLIS,
Appellees.

STATEMENT OF POINTS ON WHICH AP-
PELANT INTENDS TO RELY ON AP-
PEAL

Pursuant to the rules of the Ninth Circuit Court of Appeals the Appellant, United States of America, now designates the following points on which it intends to rely on appeal:

(1) The District Court erred in holding in substance that a District Court may not exercise all of the powers of a court of equity in a statutory injunction proceeding under 21 U.S.C. 332(a).

(2) The District Court erred in holding in substance that the Federal Food, Drug, and Cosmetic Act is not concerned with protecting the public from the payment of money for worthless drugs.

(3) The District Court erred in holding in substance that restitution may be considered a punitive remedy in that it requires a defendant to pay over monies in his possession to others.

(4) The District Court erred in holding in substance that it does not have discretionary power, ancillary to its jurisdiction to grant injunctive relief under 21 U.S.C. 332(a), to compel the defendants to refund to purchasers the money paid for the drugs involved in this action.

(5) The District Court erred in denying plaintiff's prayer in its Complaint for Injunction "that the defendants be ordered to tender to all present and past purchasers of the drugs enumerated * * * a refund of all amounts collected by said defendants from said purchasers."

Dated: This 20th day of February, 1956.

LAUGHLIN E. WATERS,
United States Attorney;

MAX F. DEUTZ,
Assistant U. S. Attorney,
Chief of Civil Division;

ARTHUR A. DICKERMAN,
Attorney, Department of Health Education and
Welfare;

By /s/ MAX F. DEUTZ,
Attorneys for Appellant.

[Endorsed]: Filed February 21, 1956.

[Title of Court of Appeals and Cause.]

STIPULATION AND ORDER FOR THE USE
OF ORIGINAL EXHIBITS IN LIEU OF
PRINTING

It Is Hereby Stipulated by and between counsel
for the Appellant and counsel for the Appellees

that, subject to the approval of this Court, the original exhibits, numbered 1 to 19, attached to the Complaint on file herein and made a part of the record on appeal to this Court, may be considered by the Court in their original form and need not be printed.

The reason for this Stipulation is that due to the length of said exhibits and the character of said exhibits it would not be feasible to print the same, and the use of the original exhibits will not impair the Court's consideration of the same.

Dated this 24th day of February, 1956.

LAUGHLIN E. WATERS,
United States Attorney;

MAX F. DEUTZ,
Assistant U. S. Attorney,
Chief of Civil Division;

ARTHUR A. DICKERMAN,
Attorney, Department of Health, Education and
Welfare;

By /s/ MAX F. DEUTZ,
Attorneys for Appellant.

DANIELS, ELSON &
MATHEWS,

/s/ EUGENE N. ELSON,
Attorneys for Appellees.

[Endorsed]: Filed February 27, 1956.